DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

Department of Veterans Affairs, Network 15 Contracting Office (NCO), 4101 S. 4th St Trafficway. Leavenworth, KS 66048. Supplies will be purchased for the John Cochran VA Medical Center and the Purchase Request number is 657-12-1423-0094 and 657-12-1-1423-0152.

2. Nature and/or Description of the Action Being Processed:

This is a Justification and Approval request for the use of other than full and open competition.

The purpose of this J&A request is to provide for the continued uninterrupted supply of direct patient care items required by the Facility.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

Estimated cost:

\$134,835.00

Delivery Need Date: 12-29-2011

Contractor:

ev3, Inc, 3033 Campus Drive, Plymouth MN 55441

The requested items are endovascular devices and are used for performing directional atherectomy procedures. The requested items are ordered frequently to maintain rotating stock levels to ensure availability. The medical center Logistics Department is requesting the stock items to replenish inventory levels to support the cardiology services department.

4. Statutory Authority Permitting Other than Full and Open Competition:

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4;
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

There are only 4 types of such devices that debulk plaque and they all work very differently. There is no mass production and all 4 devices come from 4 different companies. There is no comparative data stating that one device is better than another and use of the devices is operator specific. In the professional opinion of the medical center physician, the ev3 devices are best to facilitate the prescribed medical treatment performed by the requesting department.

Competition at this time for the required items would result in unacceptable delays and costs to the VA and ultimate harm to the Veteran patients served by the respective department.

<u>6.</u> <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:</u>

The requesting service product requirements and usage is currently being researched and reviewed by the station Logistics Department for the negotiation of a supply contract.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The requesting service and CO determined the cost to the government to be fair and reasonable based upon available historical cost data.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Internet searches and discussions with requesting service physician indicate that ev3 is currently the only producer in the marketplace of directional atherectomy devices. Industry surveillance is ongoing and additional market research will be conducted for the intended eventual contracts.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

None

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

None

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any
Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

The requirement is currently being researched and reviewed by the Logistics and NCO for the eventual negotiation of a supply contract for these Items.

12. Requirements Certification:

I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Name Eric Miller, Supervisor-Cardiac Catheterization Labs-St Louis VAMC-John Cochran

Date 12-22-2011

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NETWORK 15 CONTRACTING OFFICE

a.	<u>Contracting Officer's Certification:</u> (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.		
CONTI	Lori Kopacy Veishaar RACTING OFFICER ORK 15 CONTRACTING OFFICE	Date 12/23/11	
b.	NCM/PCM: I certify the justification meets require	ements for other than full and open competit	tion.
BERN	ADETTE COTHERN ORK CONTRACT MANAGER	Date 12-23-2011	